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JC13 Rec'd PCT/PTO 06 APR 2005

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4 October 2004

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Vat No: dk 21490601

International Patent Application No. PCT/DK03/00686
A polymeric product
Artificial A/S
Our ref.: P688PC00 – MNN/stc

Dear S. Pilling,

We refer to the first written opinion dated 08 July 2004.

The applicant respectfully requests that the Examiner acknowledges novelty, inventive step and industrial applicability of the claims as described below. In case the Examiner intends to issue a preliminary examination report not acknowledging novelty and inventive step of the claimed invention, the applicant requests either

- a telephone interview (Rule 66.6 PCT) or
- a second written opinion.

Inventive step

The present invention describes a medical device with three layers of bio-compatible polymers with the following features of claim 1:

- at least one upper layer of a first polymeric component,
 - a middle layer of a second polymeric component, and
 - at least one lower layer of a third polymeric component,
- wherein the chain length of the first polymeric component and the third polymeric component is longer than the chain length of the second polymeric component.

D1 (WO 0145595) describes a prosthetic device for insertion into a joint cavity of a joint of a vertebrate, where the device comprising at least a first longer polymeric component and a second shorter polymeric component (claim 1).

The prosthetic device of D1 can have a multiplicity of designs:

- The structure of the material of the device or of a part of the device may be in the form of fibres and filaments which can be incorporated into the matrix in a
 - braided,
 - woven,
 - spongy or
 - spiral pattern (page 10, lines 12-14).
- The structure of the material of the device may comprise
 - a layered or laminated structure,
 - a core of one material
 - or one or more interposed layers with different properties (page 10, lines 20-21).

Starting from D1 with the objective technical problem to increase the tensile strength of medical devices, there is not a solution nor an indication of a solution in D1 to this problem, nor is there an indication of a solution resulting in the solution given in the present invention.

D1 does not teach of how the strength of the device can be further increased.

Furthermore, D1 teaches away from using a layered structure by stating: "However, it is preferred that the material itself does not comprise interposed layers resulting in sliding between the layers and thereby tear on the mating surfaces within the device. Accordingly, the body of the device should be one continuous solid or semi-solid material" (page 10, lines 25-28). From this paragraph the skilled person is taught that different complications may occur when using a layered structure, and the skilled person is thus warned of using a layered composition.

In D1 a third polymer is mentioned. This polymer is grafted to the body of the device and result in improved surface properties (page 20, lines 13-14), thus the third polymer is not used to increase the tensile strength of the device and hereby the skilled person is not taught that a layer of a third polymer can be used to increase the strength of the prosthetic device.

The present invention improves the features of wear resistance, strength and toughness and it reduces the amount of tearing off. This is stated in the application by:

- "The present invention provides a desirable balance of improved wear resistance and high tensile strength and toughness in the polymeric compositions used for medical devices" (page 9, lines 4-6) and
- "The products of the invention has a high tensile strength and improved wear resistance as well as the capability to absorb shocks, impacts and pressure load, also it reduces the amount of tearing off" (page 9, lines 10-12).

Starting from D1 and stating that the solution of the technical problem as described above, is solved by the present invention in an obvious way, is pure hindsight, as D1 does not teach that this solution improves the features of wear resistance, strength and toughness of the device.

As explained the present invention does involve an inventive step in regard of D1.

Yours sincerely,
HØIBERG A/S


Malene Nielsen

Enclosed: Form 1037